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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,338	02/27/2002	Tomohiro Yasuda	HIRA.0027	8246
7590	03/22/2004		EXAMINER	
Stanley P. Fisher Reed Smith LLP 3110 Fairview Park Drive, Suite 1400 Falls Church, VA 22042-4503				MAHATAN, CHANNING
		ART UNIT	PAPER NUMBER	1631

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,338	YASUDA ET AL.	
	Examiner Channing S Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) 11 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 February 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1 Sheet</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-12.

Claim Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. Claim 10 recites “two-way lists are used to implement said consensus sequence”, however, no further steps are set forth for the implementation (Also, refer to below 35 U.S.C. § 112 2nd Paragraph Rejection). See for example *Ex parte Dunki*, 153 U.S.P.Q. 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 U.S.P.Q. 475 (D.D.C. 1966).

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph. The claimed invention is directed to a “method for assembling nucleic acid base sequences”. The instant claims recite the step of “determining whether the second nucleic acid base sequence searched in said step and the first nucleic acid base sequence can be assembled”. However, absent from the instant claims and the disclosure is guidance, direction, or examples for the above determination step. In the absence procedures for performing the above determination step one skilled in the art would not

understand how to assess if the second nucleic acid base sequence and the first nucleic acid base sequence can or cannot be assembled, thereby performing the further steps (i.e. assembling the first and second nucleic acid base sequence if it is determined that the sequences can be assembled). No procedures for “determining whether the second nucleic acid base sequence searched in said step and the first nucleic acid base sequence can be assembled” appear to be disclosed. None appear to have been known in the art. Thus, no guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1 and 2 recite the language “in said step” which is confusing. It is unclear the step Applicants’ are referring to. Applicants’ can resolve this issue by particularly pointing out what step the “said step” language is referring to. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1-3, 5-9, 11, and all claims dependent therefrom recite the limitations “partial sequence”/“fixed length partial sequence” which is vague and indefinite. The limitation “partial sequence” implies a range of values/criteria that is considered a “partial sequence”. Applicants

can resolve this issue by indicating the range of values/criteria that is considered partial.

Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 3, 5, and all claims dependent therefrom recite the limitation “matching with a part of said consensus sequence”/ “...a partial sequence matching with a sequence defined by said fixed length window with reference to said table” which is vague and indefinite. A possible interpretation is that in order to be matching it must be of the same length and be fully matching to the entire sequence. Another interpretation is that anything is considered to be matching including those with less than 100% sequence matching (i.e. 90%, 50%, etc). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 3, 5, and all claims dependent therefrom recite the limitation “...both of which are associated with each other” which is vague and indefinite. It is unclear the criteria(s) that establishes “identification information” and “fixed-length partial sequence” to be associated with each other. Applicants can resolve this issue by particularly pointing out the criteria that formulates said association. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 4, 5, and all claims dependent therefrom recite the limitation “... unprocessed nucleic acid base sequences” which is confusing. The limitation “unprocessed” implies that there is processed nucleic acid base sequences and therefore are distinguishing features that separates “unprocessed nucleic acid base sequences” from that of processed nucleic acid sequences. It should be noted the instant claim language does not indicate processed nucleic acid base sequences. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 6, 7, and 9 recite “The method for assembling nucleic acid base sequences according to claim 3 comprising...” which is vague and indefinite. It is unclear if said claims (6, 7, 9) are intended to be “further comprising” the steps of or are to further limit particular steps within the instant claim 3. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 5, 7, and all claims dependent therefrom recites the limitation “...head and tail region...” which is vague and indefinite. It is unclear what Applicants regard as the head and tail region, via characteristics/parameter. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 9 recites the limitation “...entries which are detected upon once making reference to said table and their associated input sequences...” which is vague and indefinite. It is unclear the criteria that establishes the association of the entries with input sequences. Applicants can resolve this issue by particularly pointing out the criteria that formulates said association. Clarification of the metes and bounds, via clearer claim language, is requested.

USE CLAIM

Claim 10 provides for the use of “two-way lists”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicants are intending to encompass. Claim 10 recites “two-way lists are used to implement said consensus sequence” with no further steps of implementation. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

OBJECTION TO CLAIM

Claim 11 is objected to because of a typographical error. It appears the instant claim language "...wherein a said..." should be replaced with "...wherein said...". Appropriate correction is requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

Marianne P. Allen
MARIANNE P. ALLEN 3/18/04
PRIMARY EXAMINER

A91631